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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,088	12/11/2003	Gregory L. Sundberg	279.646US1	7977

21186 7590 05/06/2009

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EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
05/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,088	SUNDBERG, GREGORY L.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,21-26 and 43-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-7, 21-26 & 43-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 1-3, 5-7, 23-24, 43-47, 51-52 & 55-60** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Due to the claim limitation of claim 1, "…compression features…define a substantially free space…" in combination with the other elements in the claim(s), the above claims fail to comply with the written description requirement since there is neither support for the above claim limitations in the specification nor the drawings.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-3, 5-7, 23-24, 43-47, 51-52 & 55-60** are rejected under 35 U.S.C. 102(b) as being anticipated by Cross et al. (US 5,935,159).

Cross et al. discloses an apparatus an implantable lead comprising (e.g., Fig 1, 10) a tubular lead body (e.g., Fig 2, 10) defining an interior lumen extending through said lead body (e.g., Fig 2, 100) so as to further define a hollow between an inner body surface and a material defining said interior lumen of the lead body; at least one electrode and at least one conductor [e.g., (Fig 1, 18 & 20) & (Fig 3, 104-110)] and at least one filler disposed in the hollow (e.g., Fig 2 & 3, 102), the filler defining a plurality of recesses in contact with the material of said interior lumen (e.g., Fig 2, 190-196), the recess include compression features and each define a free space [e.g., (col 2, ln 33-66) & (Fig 2, 180-186)]. Note that the disclosed elongated lead body contains an outer insulative tube that defines an inner, cylindrically shape in which the disclosed core member extends through, providing the claimed inner body surface and material defining an interior lumen. The Examiner is interpreting the disclose core member within the outer insulative tube as the claimed inner body surface defining a hollow which a filler is disposed within (e.g., Fig 3, 100 & 102). Also note, the Examiner is interpreting the disclosed grooves of the core as being the claimed recesses (e.g., Fig 2, 102 & 190-196).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cross et al. (US 5,935,159) and one of ordinary skill in the art.

Cross et al. discloses the claimed invention having an apparatus and an implantable medical lead including at least one filler except wherein said filler has a greater flexibility then the flexibility of a tubular lead body. However, Cross et al. does teach that it is known to utilize an invention relating to medical electrical leads comprising an outer, insulative tube and core extended through the disclosed outer tube, in which the Examiner is interpreting the core member as the claimed filler. Cross et al. teaches that the core may be extruded from a different plastic than the outer tube, such as being fabricated of polyurethane [e.g., (col 2, ln 33-66), (col 3, ln 10-50) & (Fig 3, 100 & 102)]. Note that it would have been well known to one of ordinary skill in the art to use a highly, more flexible polyurethane plastic, such as ETFE or PTFE, in order to construct the greater flexible filler as instantly claimed (e.g., col 3, ln 10-24). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to modify the apparatus and implantable lead as taught by Cross et al. with a filler having a greater flexibility then the flexibility of a tubular lead body as is instantly claimed since it is known in the art to that a filler having a greater flexibility then the flexibility of a tubular lead body is used to provide the predictable results pertaining to providing desired mechanical characteristics of a lead body in regards to the migration of the conductors through insulation due to repeated flexing of the lead body (e.g., col 3, ln 10-50).

5. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cross et al. (US 5,935,159) and one of ordinary skill in the art.

Cross et al. discloses the claimed invention having an apparatus and an implantable medical lead including at least one conductor except wherein said conductor includes insulation of the group including PTFE, ETFE and polyurethane. Cross et al. teaches that it is known to

utilize an invention relating to medical leads comprising of multiple coiled conductors surrounded by an outer insulative sheath [e.g., (col 2, ln 33-66)-(col 3, ln 1-9) & (Fig 3, 104-110 & 112-118)]. Note that it is well known to those of ordinary skill in the art that the disclosed outer insulative sheath may be fabricated from insulated plastics such as the claimed materials. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus and implantable medical lead as taught by Cross et al. with the use of at least one conductor including insulation of the group including PTFE, ETFE and polyurethane as instantly claimed since it was known in the art that a conductor including insulation of the group including PTFE, ETFE and polyurethane is used to provide the predictable results pertaining to providing an overall diameter for the insulated conductors so that electrical stimulus which travels through the multiple conductors is effectively applied [e.g., (col 2, ln 33-66)-(col 3, ln 1-9) & (Fig 3, 104-110 & 112-118)].

6. **Claims 49-50 & 53-54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross et al. (US 5,935,159) and one of ordinary skill in the art.

Cross et al. discloses the claimed invention having an apparatus and an implantable medical lead including at least one filler comprising recesses except wherein said apparatus and implantable medical lead further comprise a second filler disposed in a lead lumen wherein the second filler defines a plurality of recesses disposed along a portion of the second filler adjacent a coiled conductor. Cross et al. teaches that it is known to use an invention relating to medical leads further including a lead comprising an outer insulative tube body with a core member consisting of four radially extending portions disposed within the disclosed outer insulative tube, in which the core member has multiple grooves that the conductors lay within (e.g., Fig 2 & 3,

100, 102, 180-186, 190-196 & 104-110). Note that it is well known to those of ordinary skill in the art to consider to divide the disclosed extending portions into two groups to form two separate core members disposed adjacent to one another, (i.e. Fig 2, 186/184 & 180/182) therefore providing a first and second filler as is instantly claimed (e.g., Fig 2, 102 & 180-186). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and implantable medical lead as taught by Cross et al. with the use of a second filler disposed in a lead lumen wherein the second filler defines a plurality of recesses disposed along a portion of the second filler adjacent a coiled conductor as is instantly claimed since it was known in the art that a second filler disposed in a lead lumen defining a plurality of recesses is used to provide the predictable results pertaining to multiple circular cross-sections in which allows for insulated conductors having an outer diameter corresponding to the maximum width of the grooves (i.e. recesses) to be snapped into the grooves (e.g., col 2, ln 33-51).

7. **Claims 26 & 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross et al. (US 5,935,159) in view of Dahl et al. (US 5,366,496) and one of ordinary skill in the art.

Cross et al. discloses the claimed invention having an apparatus and an implantable medical device including at least one conductor except wherein said implantable lead further comprises at least one coil conductor with an outer insulation surface contacting an outer insulation surface of a cabled conductor in which the cable conductor is disposed around the coiled conductor. Dahl et al. teaches that it is known to utilize a body implantable tissue stimulation device including an elongate, flexible electrically conductive lead further comprising a shunt cable conductor with a dielectric sheath surrounding a conductive core in which also

includes a dielectric coating [e.g., (col 2, ln 43-49), (col 8, ln 18-27), (col 9, 36-51-64) & (Fig 6, 194, 200, 198 & 196)]. Note that it is well known in the art that the disclosed conductive core may be in the form of a coiled conductor as is instantly claimed (e.g., Fig 6, 198). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and implantable medical lead as taught by Cross et al. with the use of the shunt cable conductor surrounding a conductive core as taught by Dahl et al. since such a modification would provide the an apparatus and an implantable medical device including at least one conductor with at least one coil conductor with an outer insulation surface contacting an outer insulation surface of a cabled conductor in which the cable conductor is disposed around the coiled conductor for providing the predictable results pertaining to providing a highly conductive and fatigue-resisting conductor assembly in which provides parallel electrically conductive paths for increased electrode conductivity (Dahl, col 3, ln 29-32 & 51-64).

Response to Arguments

8. Applicant's arguments with respect to claims 1-3, 5-7, 21-26 & 43-60 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendments.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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